

GENERAL INSTRUCTIONS

This guidance provides general instructions and guidance for completing the GTEEx Donor Eligibility Criteria Form (PM-0003-F4) which is used to determine acceptability of a potential donor into the GTEEx study.

At the top of the form you will notice the direction: Answer until you reach “STOP”, “GTEEx eligible” or until you reach the end of the form. When proceeding through the form, you will notice that most questions have answers that either lead to the next question or inform you that the answer you chose has disqualified the potential donor for inclusion into GTEEx. Please read these questions and answers carefully as sometimes answers appear similar to others.

Please note: Documenting additional information or comments in the *General Comments* field (question 59) is not required. Examples of information that can be documented in the General Comments field include: explanation of information otherwise specified on another form, explanation of an *Informational Purposes Only* section question or other information the site deems pertinent to the participants history as it relates to eligibility questions.

[Create Donor Eligibility Criteria Form](#)

Note: Complete all questions for documentation of screening and eligibility of donor. Please submit for ALL screened AND enrolled subjects.

Note: Donor is ineligible if any box is checked in the ineligible column

	Eligible	Ineligible
1. Does the consent form allow for the minimum number of organs/tissue types (skeletal muscle, tibial nerve, tibial artery, skin and adipose tissue) to be collected?	<input type="radio"/> Yes	<input type="radio"/> No
2. Donor is >= 21 or <= 70 years of age	<input type="radio"/> Yes	<input type="radio"/> No
3. Donor BMI is >= 18.5 and <= 35 (BMI = 703 * weight in # /height in inches squared)	<input type="radio"/> Yes	<input type="radio"/> No
4. Is it likely that tissue collection can be completed within 24 hours of cardiac cessation (observed or presumed) or within 4 hours of clamp time for surgical collections?	<input type="radio"/> Yes	<input type="radio"/> No
5. Did donor receive a whole blood transfusion within the previous 48 hours?	<input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> Unknown
6. Has the donor ever been diagnosed with metastatic cancer (cancer that spread beyond the initial site, such as to other organs like brain, bone, or liver)	<input type="radio"/> No	<input type="radio"/> Yes
7. Has the donor received chemotherapy or radiation therapy for cancer or any other condition within the past 2 years?	<input type="radio"/> No	<input type="radio"/> Yes
8. Does the donor have a history of intravenous drug abuse in the last 5 years?	<input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes
9. Does the donor have a history of sex with someone who has been diagnosed or at risk for HIV/AIDS, and/or HCV, and/or HBV or someone who has used intravenous drugs in the last 5 years?	<input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes
10. Has the donor been exposed to HIV/AIDS, and/or HCV, and/or HBV through needle sticks, and/or contact with non-intact skin and/or contact with open wounds, and/or contact with mucous membranes? "	<input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes
11. Does the donor have a history of repeatedly reactive screening assays for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays?	<input type="radio"/> No <input type="radio"/> Unknown	<input type="radio"/> Yes



FOR INFORMATIONAL PURPOSES ONLY

The items below are not exclusionary criteria. Please complete for all screened subjects.

12. History of any of the following at the time of death	
Documented Sepsis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Pneumonia	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Open Wounds	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
High Unexplained Fever	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Positive Blood Cultures	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Abnormal WBC	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Infected Lines	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Fungal Infections	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Ascities	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Cellulites	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
13. Has blood donation been denied in the past, specify below:	
If Yes, Reason: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
14. Blood transfusion received in another country	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
15. Received a human and/or animal tissue and/or organ transplant or xenotransplant. If yes, specify in comments below:	
Comments: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
16. Recent smallpox vaccination	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
17. Contact with someone who has recently had smallpox	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
18. Dialysis treatment (long term greater than 1 month @ 3 times per week)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
19. Current diagnosis of cancer (regardless of treatment and location)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
20. Cancer diagnosis within the preceding 5 years (regardless of treatment and location)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
21. TB History	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
22. Active meningitis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
23. Active encephalitis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
24. Long term steroid use	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
25. Osteomyelitis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
26. Unexplained seizures	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
27. Unexplained weakness and fatigue described as flu-like symptoms	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
28. Exposure to toxic substances that may have led to chronic conditions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
29. No physical activity defined as bed bound for greater than 4 weeks	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
30. Resided on a Northern European military base for 6 months from 1980-1990 or elsewhere in Europe from 1980-1996	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
31. Bite from an animal suspected to have rabies in the last 12 months	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
32. Heroin use - EVER - by any route	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
33. Cocaine use in the past 5 years	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
34. Men who have sex with men	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
35. Drug injection(s) (intravenous, intramuscular, and subcutaneous) for non-medical use in the last 5 years	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
36. Hemophilia and/or clotting disorders requiring treatment with human-derived clotting factors	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
37. Performed sexual acts in exchange for money or drugs	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown



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38. Sexual activity with another person who has a history of:

Men who have sex with men

Utilized drug injections (intravenous and/or intramuscular and/or subcutaneous) for non-medical use in the last 5 years

Hemophilia and/or clotting disorders requiring treatment with human-derived clotting factors

Performed sexual acts in exchange for money or drugs

Yes No Unknown

Yes No Unknown

Yes No Unknown

Yes No Unknown

39. Was not able to be tested for HIV infection because of hemodilution where no pre-transfused specimen is available

Yes No Unknown

40. History, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior such as:

Unexplained weight loss

Yes No Unknown

Night sweats

Yes No Unknown

Blue or purple spots on the skin or mucus membranes (typical of Kaposi's sarcoma)

Yes No Unknown

Unexplained lymphadenopathy lasting more than one month

Yes No Unknown

Unexplained temperature ≥ 100.5 F (38.6 C) for more than 10 days

Yes No Unknown

Unexplained persistent cough and/or shortness of breath

Yes No Unknown

Opportunistic infections

Yes No Unknown

Sexually transmitted diseases

Yes No Unknown

Needle tracks and/or other signs of drug abuse

Yes No Unknown

41. Diagnosis of SARS or recent contact with someone who has it

Yes No Unknown

42. History of West Nile Virus (WNV)

Yes No Unknown

43. History of contact with someone who has West Nile Virus (WNV) (including animals)

Yes No Unknown

44. Unexplained weight loss

Yes No Unknown

45. Spending >72 hours in a correction/detention center in the last 12 months

Yes No Unknown

46. Tattoos done in the last 12 months (professionally) if done in a state that does not regulate tattoo parlors

Yes No Unknown

47. Received human growth hormone

Yes No Unknown

48. Prescription pill use that are not prescribed to the donor

Yes No Unknown

49. Intravenous Drug Abuse (IVDA) in the past 5 years

Yes No Unknown

50. Current infection or treatment in the last 12 months for syphilis

Yes No Unknown

51. Current infection or treatment in the last 12 months for gonorrhea

Yes No Unknown

52. Living or close physical contact with someone in the last 12 months who has been diagnosed with:

Hepatitis B

Yes No Unknown

Hepatitis C

Yes No Unknown

HIV

Yes No Unknown

53. Three or more months cumulatively spent in the UK any time from 1980-1996

Yes No Unknown

54. Non-professional piercing

Yes No Unknown

55. Non-professional tattoos

Yes No Unknown

56. A resident of a state run group home at time of death

Yes No Unknown

57. Living in Europe for 5 or more years cumulatively since 1980

Yes No Unknown



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58. History of any of the following autoimmune or degenerative neurological disease:

Systemic Lupus

Yes No Unknown

Sarcoidosis

Yes No Unknown

Scleroderma

Yes No Unknown

Reyes Syndrome

Yes No Unknown

Rheumatoid Arthritis

Yes No Unknown

Heart Disease (Idiopathic)

Yes No Unknown

Alzheimer's Disease

Yes No Unknown

Dementia with unknown cause (not from a previous CVA, infection, head trauma, or brain tumor)

Yes No Unknown

MS Multiple Sclerosis

Yes No Unknown

ALS Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease)

Yes No Unknown

Creutzfeldt-Jakob or risk factors/blood relatives being diagnosed

Yes No Unknown

59. General Comments